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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA, EASTERN DIVISION

ROBERT BODILY,

Plaintiff,

v.

WRIGHT MEDICAL TECHNOLOGY,
INC., and MICROPORT
ORTHOPEDICS, INC.

Defendant.

Case No.
COMPLAINT FOR DAMAGES

1. Strict Products Liability –
Manufacturing Defect
2. Strict Products Liability – Failure to
Warn
3. Negligence
4. Negligence – Failure to Recall/Retrofit
5. Breach of Express Warranty
6. Breach of Implied Warranty
7. Fraudulent Misrepresentation
8. Fraudulent Concealment
9. Negligent Misrepresentation

REQUEST FOR JURY TRIAL

COMES NOW plaintiff ROBERT BODILY for causes of action against
Defendants WRIGHT MEDICAL TECHNOLOGY, INC., and MICROPORT
ORTHOPEDICS, INC., who complains and alleges as follows:

1 1. At relevant times hereto, Plaintiff, Robert D. Bodily, was and is an adult
2 resident and citizen of the State of California, residing in the County of San Bernardino,
3 at 154 East 4th Street, Apt. A, San Bernardino, California 92410.

4 2. Defendant Wright Medical Technology, Inc., is a Delaware corporation,
5 with its principal place of business at 1023 Cherry Road, Memphis, Tennessee 38117.

6 3. Defendant Wright Medical Technology, Inc., is registered to do business
7 in the state of California, and at all times relevant hereto did business in the State of
8 California.

9 4. Defendant Wright Medical Technology, Inc., at times relevant hereto, was
10 engaged in the business of designing, manufacturing, distributing, selling, marketing
11 and/or introducing into interstate commerce, either directly or indirectly through third-
12 parties or related entities, various prosthetic orthopedic products, including the Wright
13 Medical Profemur® Hip products that are in issue in this civil action.

14 5. MicroPort Orthopedics, Inc., is a Delaware corporation with its principal
15 place of business at 5677 Airline Road, Arlington, Tennessee, 38002, and as such is a
16 citizen of the State of Delaware and is a citizen of the State of Tennessee.

17 6. Defendant MicroPort Orthopedics, Inc., at times relevant hereto, was
18 responsible for conducting post-market surveillance, monitoring, reporting adverse
19 events, and response to post-market surveillance issues related to the Wright Medical
20 CoCr Profemur® modular neck.

21 **JURISDICTION & VENUE**

22 7. At times relevant hereto, Defendant Wright Medical Technology, Inc., was
23 doing business in the State of California and/or is otherwise subject to the jurisdiction
24 of courts in the State of California, including this United States Federal District Court.

25 8. At times relevant hereto, Defendant MicroPort Orthopedics, Inc., was
26 doing business in the State of California and/or is otherwise subject to the jurisdiction
27 of courts in the State of California, including this United States Federal District Court.
28

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9. The injury to the Plaintiff, directly and proximately caused by the Defendants' defective product, occurred in San Bernardino County, California.

10. Venue is proper in this District pursuant to 28 U.S.C. § 1391(a) and (c), as a substantial part of the events giving rise to this claim occurred in San Bernardino County, in the State of California.

11. This United States Federal District Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332(a) as the parties are citizens of different States, and the amount in controversy exceeds the sum or value of \$75,000, exclusive of interest and costs.

12. Venue is proper in this United States Federal District Court pursuant to 28 U.S.C. § 1391(a) and (c), as a substantial part of the events giving rise to this claim occurred in San Bernardino County in the State of California.

FACTUAL ALLEGATIONS

PLAINTIFF ROBERT D. BODILY'S PROFEMUR HIP

13. On December 3, 2012, Plaintiff Robert D. Bodily had a Wright Medical artificial hip implanted in his left hip in a procedure known as a total hip arthroplasty (THA).

14. Rolf Drinhaus, M.D. was the surgeon who implanted Plaintiff's Wright Medical artificial hip.

15. Plaintiff's December 3, 2012 hip implant surgery was performed at Riverside County Regional Medical Center in Moreno Valley, California.

16. Rolf Drinhaus, M.D. did not violate any generally accepted standards of care in the field of orthopedic surgery in his care and treatment of Plaintiff in any of the following respects:

- (a) In the care or treatment that he provided to Plaintiff prior to beginning the hip implant surgery;
- (b) In the information that he did or did not provide Plaintiff prior to beginning the hip implant surgery;

- 1
- 2 (c) In the selection of the Wright Medical CoCr Profemur[®] modular
- 3 neck, or any other Wright Medical artificial hip devices, that were
- 4 implanted in Plaintiff;
- 5 (d) In the hip implant surgery he performed on Plaintiff;
- 6 (e) In the care or treatment that he provided to Plaintiff, subsequent to
- 7 Plaintiff's hip implant surgery; and,
- 8 (f) In the information that he did or did not provide to Plaintiff
- 9 subsequent to Plaintiff's hip implant surgery.

10 17. Based upon the patient population that the Defendant Wright Medical

11 intended their Profemur[®] artificial hip devices to be implanted in, at the time of

12 implantation with his Wright Medical Profemur[®] hip devices, Plaintiff Robert D.

13 Bodily was an appropriate patient to be implanted with the Wright Medical Profemur[®]

14 hip devices he received.

15 18. Rolf Drinhaus, M.D. recommended the Wright Medical Profemur[®] hip

16 devices to Plaintiff and indicated that the Wright Medical Profemur[®] hip devices were

17 appropriate for him.

18 19. Robert D. Bodily reasonably relied upon Rolf Drinhaus, M.D. in deciding

19 to proceed with hip replacement surgery and have Wright Medical Profemur[®] hip

20 devices implanted in him.

21 20. "Patient Testimonials" and "Patient Stories" published by Defendant

22 Wright Medical on Wright Medical's internet website promoting Wright Medical's hip

23 products illustrate and demonstrate the patient population, and activity levels, that

24 Wright Medical intended for its Profemur[®] Dynasty[®] and Conserve[®] hip devices.

25 21. Before or during the course of the Plaintiff's December 3, 2012 surgery,

26 Defendant, arranged for the specific Wright Profemur[®], Dynasty[®] and Conserve[®] hip

27 devices that were implanted in Plaintiff to be delivered to the Riverside County

28

Regional Medical Center in Moreno Valley, California and/or Dr. Drinhaus for implantation in the Plaintiff.

22. In his total hip replacement surgery on December 3, 2012, Plaintiff Robert D. Bodily had implanted in his left hip the following specific Wright Medical artificial hip devices among others:

- a. Profemur® Plus CoCr Modular Neck
Size: Long/8° VAR/VAL
Ref: PHAC-1254
Lot #: 1449433
- b. Conserve® Total BCH® Femoral Head
Size: 40mm
Ref: 38CH-4000
Lot: 1330223
- c. Dynasty® Biofoam® Shell
Size: 56mm
Ref: DSBFGF56
Lot: 1466162
- d. Dynasty® A-Class® Poly Liner
40mm
Group F
Ref: DLXP-LF40
Lot: 1453198
- e. Profemur® Z Plasma Stem
Size: 5
Ref: PHAO0268
Lot: 1460905

23. Based upon the patient population that Wright Medical intended their Profemur® hip devices to be implanted in, and when Plaintiff Robert D. Bodily had these devices implanted in him, he was an appropriate patient to be implanted with these Wright Medical Profemur®, Dynasty® and Conserve® hip devices.

1 24. Subsequent to the date of implantation of his Wright Medical artificial hip,
2 Plaintiff used his Wright Medical artificial hip in a normal and reasonably expected
3 manner.

4 25. Subsequent to the date of implantation of his Wright Medical artificial hip,
5 Plaintiff used his Wright Medical artificial hip in a manner consistent with, if not less
6 actively than, many of the representations made in “Patient Testimonials” and “Patient
7 Stories” that appeared in the Wright Medical websites.

8 26. After initial recovery from his December 3, 2012 surgery, for a period of
9 time Plaintiff’s Wright Medical artificial hip performed as expected, and the pain and
10 disability Plaintiff had experienced in his left hip prior to his December 3, 2012 surgery
11 had been substantially relieved.

12 27. On or about the date of January 19, 2017, approximately 49 months after
13 his December 3, 2012 implant surgery, Plaintiff Robert D. Bodily, sustained a fracture
14 of the modular neck component of his Wright Medical artificial hip.

15 28. The fracture of the modular neck component of the Plaintiff’s Wright
16 Medical hip occurred in San Bernardino County, California.

17 29. On January 20, 2017, emergency surgery, known as a “revision” surgery,
18 was performed at Riverside University Medical Center, 26520 Cactus Avenue, Moreno
19 Valley, in Riverside County, California, on Plaintiff Robert D. Bodily’s left hip by
20 Christopher Sherman, D.O., to remove and replace the failed and damaged components
21 of his Wright Medical artificial hip.

22 30. Plaintiff’s January 20, 2017, revision hip surgery, was performed at
23 Riverside University Medical Center, 26520 Cactus Avenue, Moreno Valley, in
24 Riverside County, California.

25 31. Plaintiff Robert D. Bodily’s January 20, 2017 surgery included an
26 extended trochanteric osteotomy for removal of the otherwise well-fixed femoral
27 component.

32. In the course of the revision surgery performed on January 20, 2017, Christopher Sherman, D.O., removed all of the Plaintiff's originally implanted Wright Medical hip devices, with the exception of the Dynasty® Biofoam® Shell, which was well-fixed and undamaged.

33. In the course of the revision surgery performed on January 20, 2017, a MicroPort A-Class Poly Liner, originally designed by Wright Medical, was implanted and mated with the original Wright Medical Dynasty® Biofoam® Shell. No other Wright Medical or MicroPort hip devices were implanted in the Plaintiff in his January 20, 2017 revision surgery.

34. With the exception of the fact that the Modular Neck component of Plaintiff's artificial hip had fractured, at the time of Plaintiff's revision surgery each of the devices of Plaintiff's Wright Medical hip was in substantially the same condition in all relevant respects as when they left the Wright Medical Defendant's control.

35. With the exception of the fact that the CoCr Modular Neck component of Plaintiff's artificial hip had fractured and caused injury to the Plaintiff, at the time of his revision on January 20, 2017, Plaintiff's Wright Medical hip was not otherwise in need of hip revision surgery.

ACCRUAL OF PLAINTIFF'S CAUSES OF ACTION

36. Prior to January 19, 2017, Plaintiff had neither knowledge nor notice that there was any defect in the design, manufacture or labeling of his implanted Profemur® Plus CoCr Modular Neck.

37. Prior to January 19, 2017, Plaintiff had neither knowledge nor notice that he had suffered any injury because of any negligence, actions or inactions, errors or omissions, by any of the defendants.

38. It was not until January 19, 2017 that Plaintiff first had any notice or knowledge that his injuries and/or that the failure of the Profemur® Plus CoCr Modular Neck implanted in his left hip was the result of any defects in the design, manufacture, warning or labeling of his implanted Profemur® Plus CoCr Modular Neck.

39. Prior to January 19, 2017, Plaintiff did not know, and could not have known by the exercise of reasonable diligence, that his left hip had been injured by a defect in his Profemur® Plus CoCr Modular Neck.

40. Prior to January 19, 2017, Plaintiff did not know and could not have known by the exercise of reasonable diligence of any cause of any injury to his left hip was a direct or proximate result of a defect in his Profemur® Plus CoCr Modular Neck.

41. Prior to January 19, 2017, Plaintiff had no reason to know or suspect that the hip implanted in his left hip was defective.

42. Plaintiff's causes of action alleged in this Complaint therefore did not accrue until January 19, 2017.

WRIGHT MEDICAL and MICROPORT

43. In approximately the year 1985 a European manufacturer of artificial hip devices, known as Cremascoli Ortho Group ("Cremascoli"), which had designed and manufactured artificial hips, developed the first prototype series of the titanium Profemur® Modular Necks.

44. Profemur® Modular Necks were first patented by Cremascoli, and marketed by it in 1986.

45. In December 1999, Defendant Wright Medical Group, Inc., acquired Cremascoli Ortho, acquiring its product lines, documents, and manufacturing facilities, including the Profemur® line of hip products.

46. After the acquisition of Cremascoli, Wright Medical expanded the Profemur® modular artificial hip stem and modular neck product line to include additional models or versions of Profemur® Stems and Profemur® Modular Necks.

47. After the acquisition of Cremascoli, Wright Medical branded what is at times referred to by Wright Medical as the Wright Medical Profemur® Total Hip System.

48. In 2001, a "re-styling" of the Profemur® Modular Necks' mid-body improved the allowed range of motion.

1 49. From the time Profemur® Modular Necks were first introduced to the
2 United States, through the date of August 25, 2009, the 2001 “restyled” Profemur®
3 Modular Necks were the only design or style of the modular necks that were distributed
4 or sold in the United States.

5 50. Sometime on or about the time Profemur® Modular Necks were introduced
6 to the United States, Defendant Wright Medical began to promote and market those
7 devices to physicians, and to the general public, on and through internet website pages
8 that it published and controlled.

9 51. Sometime after the date of August 25, 2009, Wright Medical began to
10 offer for distribution and sale in the United States Profemur® Modular Necks made of a
11 cobalt-chrome alloy [CoCr].

12 52. The Wright Medical CoCr Profemur® Modular Necks were intended to be
13 an alternative for the 2001 “restyled” Wright Medical titanium Profemur® Modular
14 Necks, compatible with all of the same Wright Medical Profemur® stems and Wright
15 Medical Conserve femoral heads.

16 53. In the year 2014, the Wright Medical OrthoRecon operating segment, was
17 sold by Wright Medical to a foreign entity known as MicroPort Scientific Corporation,
18 for approximately \$285 million.

19 54. In its form 10-Q, filed with the United States Securities and Exchange
20 Commission, for the quarter ended March 31, 2014, Wright Medical Group, Inc., states:

21 On January 9, 2014, pursuant to the previously disclosed Asset Purchase
22 Agreement, dated as of June 18, 2013 (the Purchase Agreement), by and
23 among us, MicroPort Scientific Corporation, a corporation formed under
24 the laws of the Cayman Islands (MicroPort), and MicroPort Medical B.V.,
25 a besloten vennootschap formed under the laws of the Netherlands, we
26 completed our divestiture and sale of our business operations operating
27 under the OrthoRecon operating segment (the OrthoRecon Business) to
28 MicroPort. Pursuant to the terms of the Asset Purchase Agreement, the
purchase price (as defined in the Purchase Agreement) for the OrthoRecon
Business was approximately \$285 million (including an estimated
working capital target adjustment), which MicroPort paid in cash.

1
2 55. The sale by Wright Medical of the OrthoRecon operating segment
3 included the sale to MicroPort of the Wright Medical Profemur® product line and its
4 manufacturing facilities in Arlington, Tennessee.

5 56. Defendant MicroPort Orthopedics, Inc., is the successor in interest, or the
6 United States operating subsidiary of, MicroPort Scientific Corporation, that had
7 purchased the Wright Medical OrthoRecon operating segment, including the Wright
8 Medical Profemur, Conserve, and Dynasty hip product lines.

9 57. MicroPort Orthopedics, Inc., has had the obligation to conduct post-market
10 surveillance related to the Profemur hip product line since acquiring those products
11 from Wright Medical in 2014.

12 **THE WRIGHT MEDICAL PROFEMUR HIP**

13 58. Since 1985, Defendant, Wright Medical Technology, Inc., directly or
14 through its parent corporation, subsidiaries or affiliates, Wright Medical Group, Inc.,
15 Wright Medical Europe, S.A., Cremascoli Ortho, Wright Cremascoli Ortho, and others,
16 designed, manufactured, labeled, marketed, promoted, distributed, and sold in the
17 United States the artificial hips with modular components.

18 59. Sometime after December 13, 2000, Defendant Wright Medical
19 Technology, Inc. began to manufacture, label, market, promote, distribute and sell in
20 the United States the Wright Medical Profemur® Hip System and its components,
21 including the Profemur® Hip System modular heads, necks and stems.

22 60. Between the dates of December 13, 2000 and August 25, 2009 the
23 Profemur® Hip System included neck and stem components made of a titanium alloy,
24 generally known as Ti6Al4V.

25 61. In various marketing and promotional material published and distributed
26 by Wright Medical from approximately the year 2002, and into the year 2005, and
27 available to Wright Medical's sales representatives and distributors, surgeons, patients
28

1 and the general public, Wright Medical made the following representations, statements,
2 claims and guarantees about its Profemur modular necks:

3 The modular neck system, designed by Cremascoli in 1985 (U.S. Patent
4 #4,957,510), has now been successfully implanted in over 50,000 patients
5 requiring both primary and revision hip arthroplasty. Extensive laboratory
6 tests have proven that the coupling between the modular neck and femoral
7 implant guarantees:

- 8 • Structural reliability
- 9 • Absence of significant micromovement
- 10 • Absence of fretting corrosion

11 [e.g., Wright Medical Technical Monograph MH688-102 ©2002, and © 2004]

12 62. The above quoted statement by Wright Medical that it, “guaranteed . . .
13 absence of fretting corrosion,” with its Profemur modular necks was false at the time it
14 was first made.

15 63. The above quoted statement by Wright Medical that it, “guaranteed . . .
16 absence of fretting corrosion,” with its Profemur modular necks was false at the time
17 Wright Medical stopped making that statement in its printed publications in the year
18 2005.

19 64. Wright Medical has never corrected or recanted the above quoted
20 statement that it, “guaranteed . . . absence of fretting corrosion,” with its Profemur
21 modular necks.

22 65. Testing done by Wright Medical prior to the year 2003 proved that fretting
23 corrosion in fact occurred with its Profemur modular necks.

24 66. Post-market surveillance conducted by Wright Medical from the years
25 2003 through 2008 proved that fretting corrosion in fact occurred with its Profemur
26 modular necks.

27 67. Testing done by Wright Medical in 2008-2009 proved that fretting
28 corrosion in fact occurred with its Profemur modular necks.

1 68. In various marketing and promotional material published and distributed
2 by Wright Medical beginning in approximately the year 2002, and available to Wright
3 Medical's sales representatives and distributors, surgeons, patients and the general
4 public, Wright Medical made the following representations, statements, claims and
5 guarantees about its Profemur modular necks:

6 The modular neck used with the PROFEMUR™ hip has been employed
7 by Wright Cremascoli for over 15 years. The necks were designed in 1985
8 and have been successfully implanted in over 50,000 patients requiring
9 both primary and revision hip procedures. The necks are used in other
10 Wright Cremascoli hip systems besides the PROFEMUR™ hip. None of
11 the necks has experienced a clinical failure since their inception.

12 [e.g., Wright Medical Technical Monograph MH688-102 ©2002, and © 2004]

13 69. Prior to the year 2002 Wright Medical knew that for its "necks designed in
14 1985," and "used with the PROFEMUR™ hip . . . for over 15 years," the statement
15 "None of the necks has experienced a clinical failure since their inception," was false.

16 70. Wright Medical has never corrected or recanted the above quoted false
17 statements.

18 71. Wright Medical Publications containing the quoted false statements, that
19 the Wright Profemur Modular necks had been designed in 1985," had been "used with
20 the PROFEMUR™ hip . . . for over 15 years," and "None of the necks has experienced
21 a clinical failure since their inception," were distributed to orthopedic surgeons by
22 Wright Medical distributors and sales representatives with the knowledge of Wright
23 Medical employees and corporate officers.

24 72. The substance of the quoted false statements, that the Wright Profemur
25 Modular necks had been designed in 1985," had been "used with the PROFEMUR™
26 hip . . . for over 15 years," and "None of the necks has experienced a clinical failure
27 since their inception," were orally disseminated to orthopedic surgeons by Wright
28 Medical distributors, sales representatives, employees, and corporate officers.

73. After Wright Medical titanium Profemur[®] Modular Necks began to be implanted, Wright Medical began to receive reports of its Profemur[®] titanium modular necks having fractured (i.e., broken into two pieces) at the oblong taper distal end where it is seated in the Profemur[®] stem.

74. At some point in time prior to July 30, 2010, Wright Medical came to the conclusion that higher than normal rates of early failure of the long offset Profemur[®] titanium modular necks have been observed for heavyweight (>230 lbs.) patients.

75. As the number of reported Wright Medical titanium Profemur[®] modular neck fractures continued to grow, case studies appeared in medical journals reporting the fracture of Wright Medical titanium Profemur[®] modular necks.

76. As the number of reported Wright Medical titanium Profemur[®] modular neck fractures continued to grow, surgeons who had been implanting these devices began to question the safety of these devices for implantation in certain patients.

77. As the number of reported Wright Medical titanium Profemur[®] modular neck fractures continued to grow, surgeons who had been implanting these devices stopped using the Wright Medical titanium modular necks.

78. As the number of reported Wright Medical titanium Profemur[®] modular neck fractures continued to grow, Wright Medical's market share of the United States artificial hip implant market began to decline.

79. As the number of reported Wright Medical titanium Profemur[®] modular neck fractures continued to grow, Wright Medical did not acknowledge that modular neck fractures were a result of a defective design, but instead engaged in a campaign of concealment, misinformation, deceit, and fraud, misrepresenting to surgeons the facts and truth as to the numbers, rates, and reasons for its Profemur[®] modular neck fractures.

80. As the number of reported Wright Medical titanium Profemur[®] modular neck fractures continued to grow, Wright Medical did not inform surgeons that, based upon information that had been reported to the FDA MAUDE Database, using these

1 devices that the long Profemur Neck Varus/Valgus CoCr 8 Degree, part number PHA0-
2 1254, had the highest numbers of fractures, and the highest rate of fractures of the
3 modular necks.

4 81. As the number of reported Wright Medical titanium Profemur® modular
5 neck fractures continued to grow, Wright Medical did not inform surgeons using these
6 devices that, based upon information that had been reported to the FDA MAUDE
7 Database, the Profemur Plasma Z hip stem was associated with the highest numbers of
8 Profemur modular

9 82. Neck fractures, and the highest rate of Profemur modular neck fractures.

10 83. As the number of reported Wright Medical titanium Profemur® modular
11 neck fractures continued to grow, Wright Medical did not inform surgeons that, based
12 upon information that had been reported to the FDA MAUDE Database, using these
13 devices with a Wright Medical Conserve® metal femoral head on a long Profemur
14 Modular neck was associated with higher numbers of Profemur modular neck fractures,
15 and a higher rate of Profemur modular neck fractures, compared to using a ceramic
16 femoral head.

17 84. As the number of reported Wright Medical titanium Profemur® modular
18 neck fractures continued to grow, Wright Medical began to design and develop a
19 Profemur® modular neck made of a CoCr alloy.

20 85. To this day Wright Medical does not admit that there was, or is, any
21 defects in the design or manufacture of its titanium Profemur® modular necks that leads
22 to premature fracture of these modular necks.

23 86. The design, development, and introduction of Wright Medical CoCr
24 Profemur® modular necks was not done as a subsequent remedial measure for any
25 design defect in the Wright Medical titanium Profemur® modular necks.

26 87. One of the purposes of Wright Medical designing and developing a
27 Profemur® modular neck made of CoCr was to preserve its market share of the artificial
28 hip device market.

1 88. On April 16, 2009, Wright Medical submitted to the United States
2 Department of Health & Human Services, Food and Drug Administration [FDA] a
3 Section 501(k) premarket notification of intent to market a device generally identified
4 as Profemur[®] hip system modular necks made of a CoCr alloy.

5 89. On August 25, 2009, Wright Medical received clearance from the FDA to
6 distribute in the United States Profemur[®] modular necks manufactured from CoCr.

7 90. Sometime on or after August 25, 2009, Wright Medical began to offer with
8 the Profemur[®] Hip System a modular neck component made of a CoCr alloy for
9 distribution in the United States.

10 91. The CoCr alloy Profemur[®] modular necks that Wright Medical began to
11 offer to surgeons and patients included a long Profemur Varus/Valgus CoCr 8 Degree
12 neck version, part number PHAC-1254.

13 92. The CoCr alloy Profemur[®] modular necks that Wright Medical began to
14 offer to surgeons and patients did not include a warning that the titanium version of the
15 long Profemur[®] Varus/Valgus CoCr 8 Degree modular neck was the version with the
16 highest reported numbers of failures by fracture, and the highest reported rate of
17 failures by fracture.

18 93. The CoCr alloy Profemur[®] modular necks that Wright Medical began to
19 offer to surgeons and patients did not include a warning that the Profemur[®] Plasma Z
20 model of its Profemur Stems had the highest reported numbers and rates of fracture of
21 modular necks.

22 94. The CoCr alloy Profemur[®] modular necks that Wright Medical began to
23 offer to surgeons and patients did not include a warning that using its Profemur
24 modular necks with its Conserve[®] femoral heads, as opposed to using ceramic femoral
25 heads, had historically higher numbers and rates of failure by fracture of the Profemur
26 modular necks.

1 95. The Profemur® CoCr modular necks that Wright Medical designed and
2 manufactured were designed to be used with all of the same femoral heads and the
3 same Profemur hip stems as were its titanium Profemur® modular necks.

4 96. Wright Medical has stated in brochures that it published with information
5 related to its Profemur® CoCr modular necks, “Product complaint data reported to
6 Wright to date does not indicate an increased risk, as compared to traditional titanium
7 necks, of adverse events due to taper junction fretting and corrosion or fractures for
8 Profemur® CoCr Modular Necks.” [See Profemur® CoCr Modular Necks Frequently
9 Asked Questions, Wright Medical publication MH619-812.]

10 97. The statement by Wright Medical that its Profemur® CoCr modular necks
11 for that, “Product complaint data reported to Wright to date does not indicate an
12 increased risk, as compared to traditional titanium necks, of adverse events due to taper
13 junction fretting and corrosion or fractures for Profemur® CoCr Modular Necks,” was
14 not supported by unbiased or independent scientific testing.

15 98. The statement by Wright Medical that “Product complaint data reported to
16 Wright to date does not indicate an increased risk, as compared to traditional titanium
17 necks, of adverse events due to taper junction fretting and corrosion or fractures for
18 Profemur® CoCr Modular Necks” was false and misleading.

19 99. Wright Medical has stated in brochures that it published with information
20 related to its Profemur® CoCr modular necks that these CoCr modular necks would
21 result in less fretting than occurred with titanium modular necks.

22 100. Statements by Wright Medical that these CoCr Profemur® modular necks
23 would result in less fretting than occurred with titanium modular necks was not
24 supported by unbiased independent scientific testing.

25 101. Statements by Wright Medical that its CoCr Profemur® modular necks
26 would result in less fretting than occurred with titanium modular necks were false and
27 misleading.

28

1 102. The design of the Wright Medical CoCr Profemur® modular neck, when
2 coupled with the design of the Wright Medical titanium Profemur hip stems, is such
3 that the process of fretting corrosion occurs at the modular neck/stem junction.

4 103. Wright Medical has stated in brochures that it published with information
5 related to its Profemur® CoCr modular necks that the use of dissimilar metals, such as
6 the mating of a CoCr modular neck with a titanium stem, would not result in galvanic
7 corrosion (“battery effect”) at a level that would be problematic for patients.

8 104. Statements by Wright Medical that the mating of a CoCr Profemur®
9 modular neck with a titanium stem would not result in galvanic corrosion (“battery
10 effect”) at a level that would be problematic for patients, were not supported by
11 unbiased sound scientific testing.

12 105. Statements by Wright Medical that the mating of its CoCr Profemur®
13 modular necks with its Profemur® titanium stems, would not result in galvanic
14 corrosion (“battery effect”) at a level that would be problematic for patients, were false
15 and misleading.

16 106. The design of the Wright Medical Profemur® CoCr modular neck, when
17 coupled with the design of the Wright Medical titanium Profemur® hip stems is such
18 that galvanic corrosion (“battery effect”) occurs at the modular neck/stem junction.

19 107. Prior to offering its CoCr Profemur® modular necks for distribution or sale
20 in the United States, Wright Medical did not adequately test its design of CoCr
21 Profemur® modular necks for fretting corrosion after implantation in patients.

22 108. Prior to offering its CoCr Profemur® Modular Necks for distribution or
23 sale in the United States, Wright Medical did not adequately test its design of CoCr
24 Profemur® modular necks for galvanic corrosion (“battery effect”) after implantation in
25 patients.

26 109. Prior to offering its CoCr Profemur® modular necks for distribution or sale
27 in the United States, Wright Medical did not adequately test its design of CoCr
28

1 Profemur® modular necks for galvanic corrosion (“battery effect”) when mated with
 2 titanium Profemur® hip stems after implantation.

3 110. Wright Medical put its CoCr Profemur® Modular Necks on the market
 4 without having adequately tested them for *in vivo* performance to resist fretting
 5 corrosion.

6 111. Wright Medical put its CoCr Profemur® Modular Necks on the market
 7 without having adequately tested them for *in vivo* performance to resist galvanic
 8 corrosion.

9 112. Wright Medical’s taking to market its CoCr modular necks without
 10 adequate testing was done to preserve market share and its profits from the sale of its
 11 Profemur® hip products.

12 113. Wright Medical knew or should have known that as of the date of
 13 December 3, 2012, the date Plaintiff received his Wright Medical CoCr Profemur®
 14 modular neck:

- 15 a) It had not adequately tested its Profemur® CoCr Modular Necks to
 16 simulate *in vivo* performance for resistance to fretting corrosion;
- 17 b) It had not adequately tested its Profemur® CoCr Modular Necks to
 18 simulate *in vivo* performance for resistance to galvanic corrosion
 19 (“battery effect”) its Profemur® CoCr Modular Necks would be
 20 subject to fretting corrosion;
- 21 c) There was an increased risk of fretting corrosion at the neck stem
 22 junction; and,
- 23 d) There was an increased risk of galvanic corrosion (“battery effect”) at the neck stem junction.

24 114. The neck stem junctions of the Profemur® CoCr modular neck, coupled
 25 with a Profemur titanium hip stem, are subject to significant micromovement which
 26 results in significant fretting corrosion, galvanic corrosion, and metal ion release.
 27
 28

1 115. The neck stem junctions of the Profemur® CoCr modular neck, coupled
2 with a Profemur titanium hip stem, and the micromovement which results in significant
3 fretting corrosion, galvanic corrosion, and metal ion release, directly and proximately
4 causes adverse medical conditions which lead to the failure and need for revision of the
5 Plaintiff's hip.

6 116. Product complaint data reported to Wright prior to December 3, 2012 did
7 indicate an increased risk of adverse events due to taper junction fretting and corrosion
8 for Wright Medical Profemur® CoCr modular necks when coupled with Wright
9 Medical Profemur® hip stems, as compared to traditional titanium necks.

10 117. Product complaint data reported to Wright prior to December 3, 2012 did
11 indicate an increased risk of adverse events due to galvanic corrosion ("battery effect"),
12 as compared to traditional titanium necks when coupled with Wright Medical
13 Profemur® hip stems.

14 118. Based upon what Wright Medical knew or should have known as of
15 December 3, 2012, a reasonable manufacturer would have ceased the distribution of the
16 Wright Medical CoCr Profemur® modular necks prior to that date.

17 119. Based upon what Wright Medical knew or should have known as of
18 December 3, 2012, Wright Medical should have ceased the distribution of the Wright
19 Medical CoCr Profemur® modular necks prior to that date.

20 120. Based upon what Wright Medical knew or should have known as of
21 December 3, 2012, a reasonable manufacturer would have formally recalled the Wright
22 Medical CoCr Profemur® modular necks prior to that date.

23 121. Based upon what Wright Medical knew or should have known as of
24 December 3, 2012, Wright Medical should have formally recalled the Wright Medical
25 CoCr Profemur® modular necks prior to that date.

26 122. Based upon what Wright Medical knew or should have known as of
27 December 3, 2012, prior to that date a reasonable manufacturer would have published
28 information that its claims that product complaint data did not did indicate an increased

1 risk of adverse events due to taper junction fretting and corrosion for Wright Medical
2 Profemur® CoCr modular necks when coupled with Wright Medical Profemur® hip
3 stems was false.

4 123. Based upon what Wright Medical knew or should have known as of
5 December 3, 2012, prior to that date Wright Medical should have published
6 information that its claims that product complaint data did not did indicate an increased
7 risk of adverse events due to taper junction fretting and corrosion for Wright Medical
8 Profemur® CoCr modular necks when coupled with Wright Medical Profemur hip
9 stems was false.

10 124. Based upon what Wright Medical knew or should have known as of
11 December 3, 2012, prior to that date a reasonable manufacturer would have published
12 information that its claims that product complaint data did not did indicate an increased
13 risk of galvanic corrosion (“battery effect”) for Wright Medical Profemur® CoCr
14 modular necks when coupled with Wright Medical Profemur® hip stems was false.

15 125. Based upon what Wright Medical knew or should have known as of
16 December 3, 2012, prior to that date Wright Medical should have published
17 information that its claims that product complaint data did not did indicate an increased
18 risk of galvanic corrosion (“battery effect”) for Wright Medical Profemur® CoCr
19 modular necks when coupled with Wright Medical Profemur® hip stems was false.

20 126. Based upon what Wright Medical knew or should have known as of
21 December 3, 2012, prior to that date a reasonable manufacturer would have informed
22 orthopedic surgeons using its Profemur hip products that its claims that product
23 complaint data did not did indicate an increased risk of galvanic corrosion (“battery
24 effect”) for Wright Medical Profemur® CoCr modular necks when coupled with Wright
25 Medical Profemur® hip stems was false.

26 127. Based upon what Wright Medical knew or should have known as of
27 December 3, 2012, prior to that date Wright Medical should have informed orthopedic
28 surgeons using its Profemur® hip products that its claims that product complaint data

1 did not did indicate an increased risk of galvanic corrosion (“battery effect”) for Wright
2 Medical Profemur® CoCr modular necks when coupled with Wright Medical Profemur
3 hip stems was false.

4 128. The neck stem junctions of the Profemur® CoCr modular neck, coupled
5 with a Profemur® titanium hip stem, are subject to significant micromovement which
6 result in significant fretting corrosion, galvanic corrosion, and metal ion release.

7 129. The neck stem junctions of the Profemur® CoCr modular neck, coupled
8 with a Profemur® titanium hip stem, and the micromovement which results in
9 significant fretting corrosion, galvanic corrosion, and metal ion release, directly and
10 proximately causes adverse medical conditions which lead to the failure, fracture of the
11 neck, and need for revision of the hip.

12 130. Based upon the facts and allegations set forth above, the Wright Medical
13 Profemur® CoCr modular neck and Profemur® hip stem system are defective in their
14 design in that the risks that were inherent in this product being used for hip
15 replacement, when weighed against the utility or benefit derived from the product,
16 outweigh the benefit which might have been gained by placing this defective product in
17 the body of Plaintiff Robert D. Bodily.

18 131. Based upon the facts and allegations set forth above, the Wright Medical
19 Profemur® CoCr modular neck and Profemur hip stem system are defective in their
20 manufacturing in that they do not comply with their intended design, specifications, in
21 that the risks that were inherent in this product being used for hip replacement, when
22 weighed against the utility or benefit derived from the product, outweigh the benefit
23 which might have been gained by placing this defective product in the body of Plaintiff
24 Robert D. Bodily.

25 132. Based upon the facts and allegations set forth above, the Wright Medical
26 Profemur® CoCr modular neck and Profemur® hip stem system are defective in their
27 labeling in that they do not perform as represented, and the risks that were inherent in
28 this product being used for hip replacement, when weighed against the utility or benefit

1 derived from the product, outweigh the benefit which might have been gained by
2 placing this defective product in the body of Plaintiff Robert D. Bodily

3 133. Based upon the facts and allegations set forth above, the Wright Medical
4 Profemur® CoCr modular necks are unreasonably dangerous in that the risks that were
5 inherent in this product being used for hip replacement, when weighed against the
6 utility or benefit derived from the product, outweigh the benefit which might have been
7 gained by placing this defective product in the body of Plaintiff Robert D. Bodily.

8 134. Defendant Wright Medical Technology, Inc. was negligent in their design,
9 manufacture, distribution and sale, marketing, promotion, and labeling of the Wright
10 Medical Profemur® CoCr modular neck and Profemur® hip stem system.

11 135. Defendant Wright Medical Technology, Inc. was negligent in the failure to
12 warn patients or surgeons that they had received product complaint data that did
13 indicate an increased risk of adverse events due to taper junction fretting and corrosion,
14 as compared to traditional titanium necks.

15 136. Defendant Wright Medical Technology, Inc. was negligent in the failure to
16 warn patients or surgeons that they had received product complaint data that did
17 indicate an increased risk of adverse events due to galvanic corrosion (“battery effect”),
18 as compared to traditional titanium necks.

19 137. Defendant Wright Medical Technology, Inc. was negligent in their failure
20 to cease distribution of the Wright Medical Profemur® CoCr modular neck before the
21 date of December 3, 2012.

22 138. On August 7, 2015, distributors and hospitals were informed of a
23 voluntary hip replacement recall by MicroPort Orthopedics Inc.; surgeons, managers,
24 distributors and hospitals were instructed to cease distributing and using the long
25 Profemur Neck Varus/Valgus CoCr 8 Degree, part number PHAC-1254, for hip
26 replacement surgeries.

139. On November 1, 2015, the United States Food and Drug Administration (FDA) issued a Class 1 hip replacement recall for the long MicroPort Profemur various/valgus CoCr 8 Degree modular neck, known as part number PHAC-1254.

140. Defendant Wright Medical Technology, Inc., was negligent in its failure to recall the Wright Medical Profemur CoCr modular neck before the date of December 3, 2012.

OPPRESSIVE, FRAUDULENT, MALICIOUS
AND GROSSLY NEGLIGENT CONDUCT

141. The failure of Defendant Wright Medical Technology, Inc., to warn patients or surgeons that they had received product complaint data that **did** indicate an increased risk, as compared to traditional titanium necks, of adverse events due to taper junction fretting and corrosion is clear and convincing evidence of willful, oppressive, fraudulent, and malicious conduct, was grossly negligent, and demonstrates a conscious disregard for the safety of patients.

142. The failure of Defendant Wright Medical Technology, Inc., to cease the distribution of the Wright Medical Profemur® CoCr modular neck before the date of December 3, 2012, is clear and convincing evidence of willful, oppressive, fraudulent, and malicious conduct, was grossly negligent, and demonstrates a conscious disregard for the safety of patients.

143. The failure of Defendant Wright Medical Technology, Inc., to recall the Wright Medical Profemur® CoCr modular neck before the date of December 3, 2012, is clear and convincing evidence of willful, oppressive, fraudulent, and malicious conduct, was grossly negligent, and demonstrates a conscious disregard for the safety of patients.

WARRANTIES

144. Statements and representations made by Defendant Wright Medical Technology, Inc., as set forth in this Complaint, constitutes express warranties as to the performance, durability, and capabilities of the Wright Medical CoCr Profemur

1 modular necks, and the Wright Medical artificial hip stems they were intended to be
2 used with.

3 145. By law certain implied warranties of merchantability and fitness for
4 intended use are applicable to the Wright Medical CoCr Profemur® modular necks, and
5 the Wright Medical artificial hip stems they were intended to be used with.

6 146. The failure of the Plaintiff Robert D. Bodily's Wright Medical CoCr
7 Profemur® modular neck coupled with the Plaintiff's Wright Medical hip stem was a
8 breach of the applicable express warranties of Defendant Wright Medical Technology,
9 Inc.

10 147. The failure of the Plaintiff Robert D. Bodily's Wright Medical CoCr
11 modular neck coupled with the Plaintiff's Wright Medical hip stem was a breach of the
12 applicable implied warranties of merchantability and fitness for intended use by
13 Defendant Wright Medical Technology, Inc., that are applicable to this product.

14 **PLAINTIFF'S INJURIES AND DAMAGES**

15 148. On or about January 19, 2017, due to corrosion of the oblong taper of the
16 CoCr modular neck where it seated in the pocket of the Profemur® stem, the Profemur®
17 CoCr modular neck implanted in Plaintiff Robert D. Bodily's left hip catastrophically
18 failed, breaking into two pieces, causing physical injury to the Plaintiff.

19 149. On or about January 19, 2017, the Profemur® CoCr modular neck
20 implanted in Plaintiff Robert D. Bodily's left hip catastrophically failed as a direct and
21 proximate result of the actions, conduct, negligence, and breach of warranties of
22 Defendant Wright Medical Technology, Inc., as alleged in this Complaint.

23 150. As a direct and proximate result of the conduct of Defendant Wright
24 Medical Technology, Inc., and Defendant MicroPort Orthopedics, Inc., as set forth in
25 this Complaint, Plaintiff Robert D. Bodily sustained injuries and damages including,
26 but not limited to undergoing surgery to remove and replace his failed Wright Medical
27 hip; past and future pain and anguish, both in mind and in body; permanent
28 diminishment of his ability to participate in and enjoy the affairs of life; medical bills

1 associated with the replacement procedure and recovery therefrom; future medical
 2 expenses; loss of enjoyment of life; loss of past and future earnings and earning
 3 capacity; disfigurement; physical impairment, and other injuries not fully known at this
 4 time.

5 151. Plaintiff Robert D. Bodily's injuries suffered were both factually and
 6 proximately caused by the defective product of the Defendant Wright Medical
 7 Technology, Inc.

8 152. Plaintiff Robert D. Bodily's injuries suffered were both factually and
 9 proximately caused by the unreasonably dangerous product of the Defendant Wright
 10 Medical Technology, Inc.

11 153. Plaintiff Robert D. Bodily is entitled to recover for all economic and
 12 special damages incurred, including but not limited to damages for subsequent
 13 surgeries, rehabilitative services, follow up doctor visits and all expenditures incurred
 14 as a result of the additional operations and follow up procedures.

15 154. Plaintiff Robert D. Bodily is entitled to recovery for lost wages, having
 16 been disabled and diminished ability to earn income.

17 155. Plaintiff Robert D. Bodily is entitled to compensation for permanent
 18 disability as a result of the failure of this hip replacement device which caused
 19 substantial injury.

20 156. Plaintiff Robert D. Bodily further shows that he is entitled to recover for
 21 all noneconomic and compensatory damages allowed by law, including, but not limited
 22 to, pain and suffering for all pain and suffering that he has incurred as a result of the
 23 defective product, the follow-up surgery, rehabilitation, and constant pain that occurs as
 24 a result of the failure of the product.

25 ///

26 ///

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28 ///

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LIABILITY

FIST CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT

(Against All Defendants)

Plaintiff incorporates by reference as if fully set forth verbatim each and every allegation in this Complaint.

156. At all times relevant hereto, Defendants designed, manufactured, distributed, sold, marketed and promoted the PROFEMUR® Total Hip System that was implanted in Plaintiff on or about December 2, 2012.

157. At all times relevant hereto, the PROFEMUR® Total Hip System was expected to, and did, reach prescribing physicians and consumers, including Plaintiff Robert Bodily and Plaintiff's physician, without a substantial change in the condition in which it was sold.

158. At all times relevant hereto, Plaintiff, Robert Bodily and Plaintiff's healthcare providers used the PROFEMUR® Total Hip System for its intended or reasonably foreseeable purpose.

159. At all times relevant hereto, the PROFEMUR® Total Hip System was dangerous, unsafe and defective in manufacture. Such defects included, but were not limited to an unreasonably high propensity for corrosion, fretting and fatigue under normal and expected use of the device, leading to fracture of the modular neck and catastrophic failure of the device, requiring revision surgery.

160. Plaintiffs are informed and believes, and thereupon alleges, that the PROFEMUR® Total Hip System implanted in Plaintiff Robert Bodily was defectively manufactured because it differed from the manufacturer's design and specifications, or from typical units of the same product line.

161. As a direct, legal, proximate and producing result of the defective manufacture of the PROFEMUR® Total Hip System implanted in Plaintiff Robert Bodily, Plaintiff sustained injuries as set forth above.

1 162. The dangerous, unsafe and defective manufacturing of the
2 PROFEMUR® Total Hip System implanted in Plaintiff Robert Bodily was a
3 substantial factor in causing Plaintiff's injuries as set forth above.

4 **SECOND CAUSE OF ACTION**

5 **STRICT PRODUCTS LIABILITY: FAILURE TO WARN**

6 **(Against All Defendants)**

7 Plaintiff incorporates by reference as if fully set forth verbatim each and every
8 allegation in the Complaint.

9 163. The PROFEMUR® Total Hip System was defective and unreasonably
10 dangerous when it left the possession of Defendants in that it contained warnings
11 insufficient to alert the medical community and patients, including Plaintiff s and
12 Plaintiffs' healthcare providers, to the dangerous risks associated with the
13 PROFEMUR® Total Hip System when used for its intended and reasonably
14 foreseeable purpose. The dangers and risks included, but were not limited to an
15 unreasonably high propensity for corrosion, fretting and fatigue under normal and
16 expected use of the device, leading to fracture of the modular neck and catastrophic
17 failure of the device, requiring revision surgery.

18 164. At all times relevant hereto, Plaintiffs and Plaintiffs' healthcare providers
19 used the PROFEMUR® Total Hip System for its intended or reasonably foreseeable
20 purpose.

21 165. Plaintiffs and Plaintiffs' healthcare providers could not have discovered
22 any defect in the PROFEMUR® Total Hip System through the exercise of due care.

23 166. Defendants knew or should have known, by the use of scientific
24 knowledge available before, at and after the time of manufacture, distribution and
25 sale of the PROFEMUR® Total Hip System, of potential risks and side effects
26 associated with the PROFEMUR® Total Hip System. Defendants knew or should
27 have known of the defective condition, characteristics, and risks associated with said
28 product, as previously set forth herein.

167. The warnings and instructions provided with the PROFEMUR® Total Hip System by Defendants did not adequately warn of the potential risks and side effects of the PROFEMUR® Total Hip System, which risks were known or scientifically knowable to Defendants.

168. Defendants had a continuing duty to warn the medical community and public, including Plaintiffs and Plaintiffs' healthcare providers, of the potential risks and increased failure rate associated with the PROFEMUR® Total Hip System.

169. As a direct, legal, proximate and producing result of Defendants' failure to warn, Plaintiff sustained injuries as set forth above.

170. Defendants' failure to adequately warn of the potential risks and side effects of the PROFEMUR® Total Hip System was a substantial factor in causing Plaintiff's injuries as set forth above.

THIRD CAUSE OF ACTION

NEGLIGENCE

(Against All Defendants)

Plaintiff incorporates by reference as if fully set forth verbatim each and every allegation in the Complaint.

171. Plaintiffs repeat, re-allege and hereby incorporate by reference all of the allegations and statements contained in Paragraphs 1 through 76 above, inclusive, as though fully set forth herein.

172. At all times relevant hereto, Defendants designed, manufactured, distributed, sold, marketed and promoted the PROFEMUR® Total Hip System for implantation into customers, such as Plaintiff, by physicians and surgeons in the U.S.

173. At all times relevant hereto, Defendants knew or should have known that the novel design of the PROFEMUR® Total Hip System necessitated clinical trials and other pre-marketing evaluations of risk and efficacy. Such testing would have revealed the increased risk of failure and complications associated with the PROFEMUR® Total Hip System. A reasonable manufacturer under the same or

1 similar circumstances would have conducted additional testing and evaluation of the
 2 PROFEMUR® Total Hip System's safety and performance prior to placing the
 3 PROFEMUR® Total Hip System into the stream of commerce.

4 174. At all times relevant hereto, Defendants knew or should have known of
 5 the serious complications and high failure rate associated with the PROFEMUR®
 6 Total Hip System. Despite receiving hundreds of reports of serious complications
 7 from healthcare providers, Defendants chose (1) not to perform any additional
 8 testing of the PROFEMUR® Total Hip System; (2) not to investigate other potential
 9 causes of the reported complications; (3) not to suspend sales or distribution; and (4)
 10 not to warn physicians and patients of the PROFEMUR® Total Hip System's
 11 unreasonably high propensity for corrosion, fretting and fatigue under normal and
 12 expected use of the device, leading to fracture of the modular neck and catastrophic
 13 failure of the device, requiring revision surgery.

14 175. As a direct, legal, proximate and producing cause of Defendants'
 15 negligent design, testing, manufacturing, marketing, selling, and promoting the
 16 PROFEMUR® Total Hip System, Plaintiff suffered injuries as set forth above.

17 176. Defendants' negligent design, testing, manufacturing, marketing,
 18 selling, and promoting the PROFEMUR® Total Hip System, was a substantial
 19 factor in causing Plaintiff's injuries as set forth above.

20 **FOURTH CAUSE OF ACTION**

21 **NEGLIGENCE – FAILURE TO RECALL/RETROFIT**

22 **(Against All Defendants)**

23 Plaintiff incorporates by reference as if fully set forth verbatim each and every
 24 allegation in the Complaint.

25 177. Plaintiff repeat, re-allege and hereby incorporate by reference all of the
 26 allegations and statements contained in Paragraphs 1 through 76 above, inclusive, as
 27 though fully set forth herein.
 28

178. At all times relevant hereto, Defendants knew or should have known that the design of the PROFEMUR® Total Hip System and its warnings were dangerous or were likely to be dangerous when used in an intended or reasonably foreseeable manner.

179. Despite the severity and number of complaints Defendants received, Defendants failed to recall, retrofit, or warn patients or physicians about the danger of the PROFEMUR® Total Hip System.

180. Reasonable manufacturers, distributors, sellers, promoters, and designers under the same or similar circumstances would have recalled the PROFEMUR® Total Hip System.

181. As a direct, legal, proximate and producing result of Defendants' failure to recall the PROFEMUR® Total Hip System, Plaintiff suffered injuries as set forth above.

182. Defendants' failure to recall the PROFEMUR® Total Hip System was a substantial factor in causing Plaintiffs' injuries as set forth above.

FIFTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY
(Against All Defendants)

Plaintiff incorporates by reference as if fully set forth verbatim each and every allegation in the Complaint.

183. Through sales representatives, consultants, printed materials, and other advertising and marketing efforts, Defendants made express representations to healthcare providers and patients, including Plaintiffs and Plaintiffs' healthcare providers, about the safety and efficacy of the PROFEMUR® Total Hip System.

184. The PROFEMUR® Total Hip System does not conform to the express representations made by Defendants through sales representatives, consultants, printed materials, and other advertising and marketing efforts.

185. Defendants' conduct in this manner was a contributing cause of injuries and damages suffered by Plaintiffs.

SIXTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY
(Against All Defendants)

Plaintiff incorporates by reference as if fully set forth verbatim each and every allegation in the Complaint.

186. At the time Defendants designed, tested, marketed, promoted, and sold the PROFEMUR® Total Hip System, Defendants knew of the intended, reasonably foreseeable uses and impliedly warranted the PROFEMUR® Total Hip System to be of merchantable quality and safe and fit for such use.

187. Plaintiffs and Plaintiffs' healthcare providers, in deciding to use the PROFEMUR® Total Hip System as part of Plaintiff, Robert Bodily's total hip replacement, reasonably relied upon the skill and judgment of Defendants as to whether the PROFEMUR® Total Hip System was of merchantable quality and safe and fit for its intended or reasonably foreseeable use.

188. In breach of the implied warranty given by Defendants, the PROFEMUR® Total Hip System was not of merchantable quality or safe or fit for its intended or reasonably foreseeable use because the product was unmerchantable, in a defective condition and unreasonably dangerous and unfit for its intended use. The unmerchantable, defective, and unreasonably dangerous nature of the PROFEMUR® Total Hip System included, but was not limited to, an unreasonably high propensity for corrosion, fretting and fatigue under normal and expected use of the device, leading to fracture of the modular neck and catastrophic failure of the device, requiring revision surgery.

189. As a direct, legal, proximate and producing result of Defendants' breach of warranty, Plaintiffs suffered injuries as set forth above.

SEVENTH CAUSE OF ACTION
FRAUDULENT MISREPRESENTATION
(Against All Defendants)

Plaintiff incorporates by reference as if fully set forth verbatim each and every allegation in the Complaint.

190. The Defendants falsely and fraudulently represented to the medical and healthcare community, and to Plaintiffs, Plaintiffs' healthcare providers, and/or the FDA, that the PROFEMUR® Total Hip System had been properly tested and was safe and effective for its indicated use.

191. The representations made by Defendants to the medical and healthcare community, and to Plaintiff, Plaintiff's healthcare providers, and/or the FDA, regarding the safety and performance of the PROFEMUR® Total Hip System were, in fact, false.

192. Defendants knew or should have known that the PROFEMUR® Total Hip System had not been sufficiently tested, was defectively designed, and lacked adequate warnings and instructions.

193. Defendants knew or should have known that the PROFEMUR® Total Hip System could and would cause severe and grievous injury to users of said product, and that the PROFEMUR® Total Hip System's inherent dangers exceeded any purported, inaccurate, and/or downplayed warnings.

194. When said representations were made by Defendants, Defendants knew those representations to be false and exhibited a willful, wanton and reckless disregard for the truth of said representations.

195. Said representations were made by Defendants with the intent to defraud and deceive Plaintiffs, Plaintiffs' healthcare providers, the medical community, and the general public. Defendants intended said representations to induce Plaintiffs, Plaintiffs' healthcare providers, the medical community and the general public, to recommend, implant, and/or purchase the PROFEMUR® Total

1 Hip System for use as part of total hip replacement surgery. Defendants' actions
 2 evinced a callous, reckless, willful, depraved indifference to the health, safety, and
 3 welfare of Plaintiff.

4 196. At all relevant times, Plaintiffs and Plaintiffs' healthcare providers
 5 were unaware of the falsity of said representations and reasonably believed them to
 6 be true.

7 197. In reliance upon Defendants' representations, Plaintiffs were induced
 8 and did use the PROFEMUR® Total Hip System, thereby sustaining severe and
 9 permanent personal injuries, and is now at an increased risk of sustaining further
 10 severe and permanent personal injuries in the future.

11 198. Defendants brought the PROFEMUR® Total Hip System to the
 12 market, and acted fraudulently, wantonly, and maliciously to the detriment of
 13 Plaintiff.

14 199. As a direct, legal, proximate and producing result of Defendants' false
 15 representations, Plaintiffs suffered the injuries set forth herein.

16 **EIGHT CAUSE OF ACTION**
 17 **FRAUDULENT CONCEALMENT**
 18 **(Against All Defendants)**

19 Plaintiff incorporates by reference as if fully set forth verbatim each and every
 20 allegation in the Complaint.

21 200. Defendants knew their representations were false or recklessly disregarded
 22 the truth of said representations.

23 201. In representations to Plaintiffs, Plaintiffs' healthcare providers, and/or the
 24 FDA, Defendants omitted, concealed or suppressed material information regarding the
 25 safety and performance of the PROFEMUR® Total Hip System, including, but not
 26 limited to:

- 27 (a) an unreasonably high propensity for corrosion, fretting and
 28 fatigue under normal and expected use of the device, leading to

fracture of the modular neck and catastrophic failure of the device, requiring revision surgery.

- (b) that the PROFEMUR® Total Hip System had an unacceptably high rate of failures requiring revision surgery;
- (c) that the safety and performance of the PROFEMUR® Total Hip System was not adequately tested and/or known by Defendants;
- (d) that patients implanted with the PROFEMUR® Total Hip System were at increased risk of experiencing painful and debilitating product failure and were more likely to undergo revision surgery than patients using other hip implant devices;
- (e) the PROFEMUR® Total Hip System was designed, manufactured, marketed, promoted, distributed and sold negligently, defectively, and/or improperly;
- (f) that safer alternatives were available.

202. Defendants purposefully downplayed and understated the serious nature of the risks associated with the use of the PROFEMUR® Total Hip System in order to increase and sustain sales.

203. Defendants had sole access to material facts regarding the safety and performance of the PROFEMUR® Total Hip System. Defendants knew Plaintiffs and Plaintiffs' healthcare providers and/or the FDA had no way to determine the truth behind Defendants' concealment, omission and suppression of material facts as set forth herein.

204. Plaintiffs and Plaintiffs' healthcare providers relied on Defendants' incomplete and inaccurate representations as to the safety and performance of the PROFEMUR® Total Hip System when selecting, recommending, and implanting the PROFEMUR® Total Hip System.

205. As a direct, legal, proximate and producing result of Defendants' concealment of material facts, Plaintiffs has suffered injuries as set forth herein.

NINETH CAUSE OF ACTION
NEGLIGENT MISREPRESENTATION
(Against All Defendants)

Plaintiff incorporates by reference as if fully set forth verbatim each and every allegation in the Complaint.

206. Defendants had a duty to truthfully represent to the medical community, and to Plaintiffs, Plaintiffs' healthcare providers, and the FDA, that the PROFEMUR® Total Hip System had been properly tested and found to be safe and effective for its intended use.

207. Defendants knew or should have known the representations regarding the safety and performance of the PROFEMUR® Total Hip System were, in fact, false.

208. Defendants failed to exercise ordinary care in determining the truth or falsity of their representations, and by misrepresenting the safety and performance of the PROFEMUR® Total Hip System.

209. Defendants breached their duty to present truthful representations by knowingly, or by want of ordinary care, misrepresenting the safety and performance of the PROFEMUR® Total Hip System.

210. As a direct, legal, proximate and producing result of Defendants' concealment of material facts, Plaintiffs has suffered injuries as set forth herein.

CONDUCT MERITING AN AWARD OF PUNITIVE DAMAGES

Plaintiff incorporates by reference as if fully set forth verbatim each and every allegation in the Complaint.

211. The acts and omissions of the Defendant Wright Medical Technology, Inc., as set forth herein constitute intentional, fraudulent, malicious and/or reckless conduct. Accordingly, Plaintiff is entitled to an award of punitive damages.

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DAMAGES

Plaintiff incorporates by reference as if fully set forth verbatim each and every allegation in the Complaint.

212. As a direct and proximate result of the acts and omissions of the Defendants alleged herein, Plaintiff was injured and damaged. The injuries and damages for which Plaintiff seeks compensation from the Defendants include, but are not limited to:

- a. physical pain and suffering of a past, present and future nature;
- b. emotional pain and suffering of a past, present and future nature;
- c. permanent impairment and scarring;
- d. medical bills and expenses of a past, present and future nature;
- e. loss of earnings;
- f. loss of earning capacity;
- g. loss of enjoyment of life;
- h. pre- and post-judgment interest;
- i. statutory and discretionary costs; and,
- j. all such further relief, both general and specific, to which they may be entitled to under the premises.

PRAYER FOR RELIEF

Plaintiff incorporates by reference as if fully set forth verbatim each and every allegation in the Complaint.

WHEREFORE, PREMISES CONSIDERED, Plaintiff sues the Defendant Wright Medical Technology, Inc., and Defendant MicroPort Orthopedics, Inc. for personal injuries and prays for a judgment against the Defendants for compensatory damages in an amount considered fair and reasonable by a jury, and for all such further relief, both general and specific, to which Plaintiff may be entitled under the premises.

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1 WHEREFORE, PREMISES CONSIDERED, Plaintiff sues the Defendants for
2 personal injuries and prays for a judgment against the Defendants for punitive damages
3 in an amount considered fair and reasonable by a jury, and for all such further relief,
4 both general and specific, to which they may be entitled under the premises.

5
6 **A JURY IS RESPECTFULLY DEMANDED.**

7
8
9 DATED: October 18, 2018

PANISH SHEA & BOYLE LLP

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13 By: 

14 Peter Kaufman

15 Attorneys for PLAINTIFFS
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